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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,168	12/14/2001	Hsi Liu	6395-61666	9437

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/017,168	LIU ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 102(b) of Norgard for claims 1,2, 5-7, 11-15 and 30.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Advisory Attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *1,2,5-7,11-16,28,30 and 31*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *2/20/04*.

10. ☒ Other: *Advisory Attachment and Interview Summary (5/27/2004).*

ADVISORY ATTACHMENT

1. This Office Action is responsive to Applicant's response filed June 4, 2004. It should be noted that Portnoy and Magnuson, *(J. Immunology, 75(5):348-55, 1955)* was not received with the After-Final response. It should be noted that the signed Information Disclosure Statement - FORM 1449 is submitted with this Office action. For clarification of the record the Information Disclosure Statement was filed February 20, 2004.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejection Maintained

3. The rejection under 35 U.S.C. 102(b) as anticipated by Norgard et al is maintained for claims 16 and 31 for the reasons set forth on pages 4-5, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Norgard et al teach a method of detecting *anti*-Treponema monoclonal antibodies in various body fluids in the diagnosis of syphilis (see the Abstract). Norgard et al teach that the anti-*T. pallidum* antibodies used in the assay were affinity purified (i.e. isolated from clone) (page 712). The sequence of the *T. pallidum* peptide, for example SEQ ID NO: 15 would be inherent in the teachings of the prior art. Norgard et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

greater than 1000 *T. pallidum* proteins can have numerous antibody binding sites (i.e. epitopes) and thus the number of possible anti-*T. pallidum* antibodies that could be isolated vastly exceed the thirteen monoclonal antibodies described by Norgard et al. Applicant urges that it is extremely unlikely that one of the thirteen Norgard et al antibodies is specific for the immunogenic peptide of *T. pallidum* repeat protein.

Applicant's arguments filed June 4, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that the claimed method of detecting the presence of *Treponema pallidum* in a biological sample is same as the method of detecting method the presence of *Treponema pallidum* in a biological sample of the prior art. Norgard et al teach a method of detecting antibodies to *T. pallidum.* Applicant has provided no comparison that shows that the claimed method differs from that of the prior art. It should be noted that the number of possible antibody sites (i.e. epitopes) has no relevance because the claims are direct to a method of detecting *T. pallidum* antibodies in a biological sample. There is no limitation in the claim as to how many different antibodies can be detected using the claimed method. Applicant has provided no evidence (side-by side comparison) that the *T. pallidum* antibodies as detected by Norgard et al differ from the *T. pallidum* antibodies detected in the claimed method. The method steps used in the prior art are the same as the method steps used in the claimed method. Therefore, Norgard et al anticipate the claimed method.

4. The rejection under 35 U.S.C. 102 (b) as anticipated by Hunter et al is maintained for claims 1-2, 5-7, 11-16 and 30-31 for the reasons set forth on pages 5-6, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Hunter et al teach a method of detecting syphilis in sera samples using a desoxycholated-extracted treponemal antigen (i.e. isolated) in an enzyme-linked immunosorbent assay (see the Title and the Abstract). The sequence of the *T. pallidum* peptide, for example SEQ ID NO: 15 would be inherent in the teachings of the prior art. Hunter et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Hunter et al describes a sodium desoxycholate extract of *T. pallidum* using the procedure as described by Portnoy and Magnuson. Applicant urges that neither Hunter nor Portnory and Magnuson identify the protein or other components contained in the sodium desoxycholate extract. Applicant urges that Portnoy and Magnuson expressly state that "limited information is available does not permit chemical characterization of the (desoxycholate extract)". Applicant urges that the Office admits that the extract of Hunter et al contain an unknown mixture of some fraction of *T. pallidum* proteins.

Applicant's arguments filed June 4, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record that shows that the method of detecting the presence of *T. pallidum* or anti-treponemal antibodies in a biological sample of the prior art is not the same as the claimed method.

Although the desoxycholate extract as detected by the method of the prior art contains "an unknown mixture of some fraction of *T. pallidum* proteins", this does not exclude the fact that the claimed *T. pallidum* acidic repeat protein may be included in the unidentified *T. pallidum* protein mixture. Applicant has provided no evidence that the unidentified mixture of proteins as taught by Hunter et al differs from the *T. pallidum* acidic repeat protein detected in the claimed method. The method steps used in the prior art are the same as the method steps used in the claimed method. Therefore, Hunter et al anticipate the claimed method.

5. The rejection under 35 U.S.C. 103 (a) as unpatentable over Hunter et al is maintained for claim 28 for the reasons set forth on pages 6-8, paragraph 7 of the previous Office Action.

Hunter et al teach a desoxycholated-extracted treponemal antigen (i.e. isolated) used in an enzyme-linked immunosorbent assay to detect *T. pallidum* in a biological sample (see the Title and the Abstract). In re Venezia 189 USPQ 49 (CCPA 1976), held that kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. It would be obvious to use the desoxycholated-extracted treponemal antigen used in an immunoassay of the prior art in a diagnostic kit to detect *T. pallidum* in a biological sample. It would also be obvious to include the instructions for using the kit, because it is well known in the art to include instructions with diagnostic kits.

It should be noted that the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. It is also noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03:

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant urges the in order establish a *prima facie* case of obviousness the Office must offer reference that teach or suggest all elements of the rejected claims. Applicant urges that Hunter et al do not teach or suggest all elements of claim 1. Applicant urges that all claim limitations of claim 28 are not taught or suggested by the prior art.

Applicant's arguments filed June 4, 2004 have been fully considered but they are not persuasive. In response to applicant's argument that no *prima facie* case of obviousness has not been established, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the claims are directed to a kit comprising an isolated acidic repeat protein or one or more isolated immunogenic *Treponema pallidum* peptides of the acidic repeat protein and instructions for carrying out the method according to claim 1. Hunter et al teach a desoxycholated-extracted treponemal antigen (i.e. isolated) used in an enzyme-linked immunosorbent assay to detect *T. pallidum* in a biological sample. It should be noted

that the desoxycholate extract as detected by the method of the prior art contains "an unknown mixture of some fraction of *T. pallidum* proteins", this does not exclude the fact that the claimed *T. pallidum* acidic repeat protein may be included in the unidentified *T. pallidum* protein mixture. In re Venezia 189 USPQ 49 (CCPA 1976), held that kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. It would be obvious to use the desoxycholated-extracted treponemal antigen used in an immunoassay of the prior art in a diagnostic kit to detect *T. pallidum* in a biological sample. It would also be obvious to include the instructions for using the kit, because it is well known in the art to include instructions with diagnostic kits.

Status of Claims

6. No claims allowed.

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
August 1, 2004

NITA MINNIFIELD
PRIMARY EXAMINER